

4/2/79

PP# 8F2081: Metolachlor in Corn and Soybeans. Evaluation of residue data and analytical method*

Alfred Smith, Chemist, RCB, HED (TS-769)

H. Jacoby (PM #24), HFB, RD (TS-767) and TOX, HED (TS-769)

Thru: Acting Chief, RCB

The CIBA-GEIGY Corporation proposes tolerances for combined residues of the herbicide metolachlor, [2-chloro-N(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], and its metabolites determined as (2-[(2-ethyl-6-methylphenyl)amino]-1-propanol) and (4-[2-ethyl-6-methylphenyl]-2-hydroxy-5-methyl-3-morpholinone), each expressed as metolachlor, as follows:

Corn forage and fodder	1.25 ppm
Fresh corn including sweet corn (kernels plus cobs, husks removed)	0.1 ppm
Popcorn (grain)	0.1 ppm
Soybean forage and fodder	2.0 ppm

A permanent tolerance has been established for metolachlor in corn grain (except popcorn) at 0.1 ppm (#180.368; PP# 5F1606; Federal Register, Volume 41, no. 178, 9/13/76).

Temporary tolerances are established for soybeans at 0.1 ppm; soybean hay and forage at 1.25 ppm; and, meat, eggs, and milk at 0.02 ppm (PP# 6G1708).

Permanent tolerances are pending for soybeans at 0.1 ppm and meat, milk, and eggs at 0.02 ppm (PP# 7F1913); sorghum grain at 0.3 ppm and sorghum forage and fodder at 1.5 ppm (PP# 8F2098).

Conclusions

1. The nature of the residue is adequately delineated.
2. Adequate analytical methods are available for enforcement purposes.
- 3a. Residues in soybean forage and fodder are not likely to exceed the proposed tolerance.
- 3b. No data are submitted for soybean hay. We estimate that a level of 8 ppm could be expected in hay.

Note: Pages 4 & 5 not included. See page 3 for explanation.

3c. Residues of linuron or metribuzin in or on soybean forage and fodder are not likely to be ingested by livestock due to the hay and forage feeding restrictions in registered uses.

4. Residues of metolachlor in corn forage and fodder, popcorn grain, and fresh corn, including sweet corn (kernels plus cobs, husks removed) are not likely to exceed the proposed tolerances. Additionally, residues of atrazine in these commodities are not likely to exceed the established tolerances due to the tank-mix use.

A tolerance of 1.0 ppm would be more appropriate for corn forage and fodder.

5. Metolachlor residues are likely to occur in eggs, milk, and meat of livestock due to the proposed corn and soybean tolerances [§180.6(a)(2)]. However, the proposed tolerances (PP# 7F1913) for eggs, milk, and meat of livestock are sufficient to cover residues due to the proposed and established tolerances for corn and soybeans.

Recommendation

We recommend against the proposed tolerances. A favorable recommendation is contingent upon resolution of the following deficiency.

1. No residue data are submitted for soybean hay. In the absence of such data, we estimate a level of 8 ppm metolachlor residues in the hay. Since this level exceeds that level proposed for the forage, a tolerance could be proposed to cover such residues. In the absence of a tolerance proposal, residue data for hay could be submitted to show that residues in hay do not exceed the level proposed for forage and fodder.

As an alternative, restrictions which forbid the feeding of hay may be placed on the label.

2. A tolerance of 1.0 ppm would be more appropriate for corn forage and fodder. Such a level should be proposed.

Detailed Considerations

Proposed Use

Metolachlor, formulated as Dual 6E (6 lb act/gal) and Dual 8E (8 lb act/gal), is proposed for use as a preplant incorporated or preemergence surface-applied treatment alone or tank-mixed with atrazine[®], metribuzin[®], or linuron[®] for grass and weed control in corn and soybeans.

Corn & soybeans: apply metolachlor alone at rates of 1.5-3.0 lb act/A depending upon the soil type.

Corn (tank-mix): apply in tank-mix combinations of 1.0-2.5 lb metolachlor/A + 1.0-2.5 lb atrazine/A.

Soybeans (tank-mix): apply in combinations of 1.25-2.5 lb metolachlor/A + 0.25-0.75 lb metribuzin/A, or 1.25-2.5 lb metolachlor/A + 0.5-1.5 linuron/A depending upon the soil type.

*(Atrazine is registered for preplant, and pre- and post-emergence treatments on field, sweet, and popcorn at a rate of 4 lb act/A. Tolerances for atrazine are established on the grain of field, sweet, and popcorn at 0.25 ppm and the forage and fodder at 15 ppm.

Metribuzin is registered for preemergence treatments on soybeans at rates of 0.30-1.0 lb act/A. The soybean vines are not to be used for feed or forage. A tolerance of 0.1 ppm is established for metribuzin on soybeans.

Linuron is registered for pre- and post-emergence applications on soybeans at rates of 0.25-3 lb act/A with a 60-day PHI. Treated areas are not to be grazed, and the hay or forage from treated areas is not to be fed. A tolerance of 1.0 ppm is established for linuron on soybeans.)

The formulations' inert ingredients are cleared for use under 5180.1001.

The manufacturing process and the composition of technical metolachlor is given on the following pages. The impurities are not likely to produce a residue problem.

We have considered the question of the possible presence of nitrosoamines in previous memos (PP# 7F1913) and indicated that nitrosoamine formation is unlikely.

Page 4 contains inert ingredient information and is not included here.

Page 5 contains the manufacturing process and is not included here.

Nature of the Residue

We have considered the metabolism of metolachlor in plants and animals in previous reviews (PP#s 7F1913, 6G1708, 6F1606, 5G1553). Plants (corn, soybeans) absorb, translocate, and metabolize metolachlor. The primary path of plant metabolism involves hydrolysis and conjugation with plant constituents.

Metolachlor is ingested, metabolized, and rapidly eliminated by animals (rats, goats, cattle, chickens) with some deposition of residues in tissues. While the conjugating natural components in animals differ from those in plants, the metabolic components are similar.

The nature of the residue in plants and animals is similar. The significant components of the residue consist of the parent compound and its metabolites: 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol; and, 4-[2-ethyl-6-methylphenyl]-2-hydroxy-5-methyl-3-morpholinone. The analytical method determines these components and their conjugates.

The nature of the residue is adequately delineated.

Analytical Methods

The residue methods for metolachlor and its metabolites in corn and soybeans have been fully discussed in previous reviews and found adequate for the determination of metolachlor residues (PP#s 7F1913, 5F1606). Additionally, successful method trials have been performed with corn and tissues (PP# 5F1606).

We conclude that adequate analytical methods are available for enforcement purposes.

Atrazine: the residue method is similar to the method tested successfully by FDA on corn, milk, and potatoes using atrazine and its metabolites [J. Ag. & Fd. Chem., 13, 120 (1965); PP# 7F0534]. The method is adequate for residue determinations on corn.

Metribuzin: the method has been successfully tested on soybeans by EPA and is included in PAM II as method I.

Linuron: the method is adequate for residue determinations and is included in PAM II as methods I and II.

Residue Data

Soybean forage and fodder - samples were obtained from crops in Indiana, Nebraska, Illinois, Maryland, Mississippi, Pennsylvania, Georgia, and Iowa which had been treated at the maximum proposed and 2X maximum proposed rate. At the maximum proposed rate (3 lb act/A), the green forage (collected at 30-63 days after treatment) had apparent residues of 0.13-1.69 ppm. Residues at the exaggerated rate were 0.42-1.76 ppm. The harvest forage and fodder (collected at harvest, 121-167 days after treatment) had <0.08-1.61 ppm metolachlor due to the proposed rate and

0.65-2.53 ppm due to the exaggerated rate (2X maximum). Soybean hay - no data are submitted for soybean hay. In the absence of residue data which show the level of residues expected in hay, we can estimate the level expected by assuming a residue concentration factor of 4 in going from green forage to hay. Using the proposed 2 ppm tolerance level, residues of 8 ppm would be expected in soybean hay.

The petitioner should be informed that a tolerance of 8 ppm should be proposed for the hay. As an alternative, the label could contain restrictions on the use of soybean hay as a livestock feed item. Additionally, the petitioner could submit residue data for the hay which show the level of residues expected.

Tank-mix treatments

Soybean plots were treated with metolachlor plus linuron or metolachlor plus metribuzin at the proposed tank-mix rates. For green fodder (63-90 days), metolachlor residues were 0.15-0.54 ppm. Linuron residues were <0.1-0.35 ppm, and metribuzin residues were 0.02-0.11 ppm. For dry forage or fodder (at harvest, 118-178 days), metolachlor residues were <0.08-0.65 ppm. Linuron residues were 0.06-0.17 ppm, and metribuzin residues were <0.01-0.06 ppm.

Residues of metolachlor in or on soybean forage due to the tank-mix treatments are not likely to exceed the proposed tolerance. Additionally, residues of linuron or metribuzin in or on soybean forage are not likely to be ingested by livestock due to the hay and forage feeding restrictions in registered uses.

Field Corn

Samples of corn (grain, forage and fodder) were obtained from plots in California, Illinois, Indiana, Iowa, Mississippi, Maryland, Missouri, Florida, Nebraska, New York, Ohio, Washington, Texas, and Wisconsin. The field corn plots had received treatments of metolachlor alone in the proposed manner at rates of 1.5-6.0 lb act/A (up to 2X the maximum proposed rate). Residues in forage were <0.03-0.43 ppm at intervals of 30-71 days after treatments. Residues in forage at 90-204 days were <0.03-0.73 ppm.

The field corn grain had no detectable residues (<0.10 ppm) at harvest (107-204 days after treatment from all rates).

Tank-mix treatments - metolachlor and atrazine were applied in combination at proposed rates of 2.0-2.5 lb metolachlor plus 1.6-2.0 lb atrazine per acre. No detectable residues of atrazine (<0.10 ppm) were noted in forage, fodder, or grain. No residues of metolachlor were noted at levels greater than those noted with only metolachlor treatments.

Residues of metolachlor in field corn forage and fodder and popcorn grain are not likely to exceed the proposed tolerances. However, we believe a tolerance of 1.0 ppm would be more appropriate for corn forage and fodder (this includes sweet corn as well).

Residues of atrazine in or on the grain and forage and fodder of field corn or the grain of popcorn are not likely to exceed the established tolerances due to the tank-mix use.

Sweet Corn

Samples of corn forage and fodder and corn ears (husks removed) were obtained from plots which had received metolachlor treatments alone at rates of 2-6 lb act/A (2X maximum proposed). Residues in forage were <0.05-0.91 ppm from all rates at intervals of 25-100 days after treatments. At an interval of 138 days, residues in forage were <0.03 ppm due to rates of 3 and 4 lb act/A.

Residues in corn ears were less than 0.1 ppm (no detectable residue) from all treatment rates and intervals after treatment.

Tank-mix treatments - metolachlor and atrazine were applied to sweet corn at respective rates of (2 + 1.6) lb act/A and (2.5 + 2.0) lb act/A. Atrazine residues in the forage were <0.05-0.12 ppm at 30-116 days after treatments. The ears had atrazine residues of <0.1 ppm. Metolachlor residues in the forage and ears were similar to or less than the levels noted when used alone.

We conclude that residues of metolachlor in corn forage and fodder, popcorn grain, and fresh corn including sweet corn (kernels plus cobs, husks removed) are not likely to exceed the proposed tolerances from the proposed uses. Additionally, residues of atrazine in these commodities are not likely to exceed the established tolerances from the proposed uses.

Meat and Milk

Corn grain, corn forage and fodder, and soybean forage and fodder are livestock feed items. The corn forage and fodder (1.25 ppm proposed tolerance) is the feed item likely to contribute the major portion of residues to the diet of cattle, goats, horses, and sheep. The corn grain is the feed item likely to contribute the major portion of residues to the diet of hogs and poultry.

A permanent tolerance of 0.1 ppm has been established for metolachlor in field corn grain (§180.368). Temporary tolerances are established for soybeans at 0.1 ppm; soybean hay and forage at 1.25 ppm; and, eggs, milk, meat, fat, and meat byproducts of cattle, hogs, horses, poultry, and sheep at 0.02 ppm (PP# 601708). Permanent tolerances are pending for soybeans at 0.1 ppm and eggs, milk, meat, fat, and meat byproducts of livestock at 0.02 ppm (PP# 7F1913).

The proposed and established tolerance levels for metolachlor in eggs, milk, and meat are supported by cattle, goat, and chicken feeding studies (see PP# 7F1913). These studies are sufficient to conclude that metolachlor residues are likely to occur in eggs, milk, and meat of livestock

due to the proposed corn and soybean tolerances in this petition - PP# 8P2081 [§180.6(a)(2)]. Moreover, the proposed eggs, milk, and meat tolerances are sufficient to cover residues due to the established and proposed tolerances for corn and soybeans.

Alfred Smith